DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee
February 3-4, 1986
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on February 3-4, 1986. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Dr. Ellen S. Alkon
Dr. Jeffrey P. Davis
Dr. David S. Fedson
Dr. Anne A. Gershon
Dr. D. A. Henderson
Dr. Joan K. Leavitt
Dr. Edward A. Mortimer

Ex Officio Members

Dr. William S. Jordan, Jr. (NIH)
(represented by Dr. Franklin Tyeryar)
Dr. Harry M. Meyer, Jr. (FDA)
(represented by Dr. Elaine Esber)

Liaison Representatives

Dr. Philip A. Brunell (AAP)
Dr. Jarrett Clinton (DOD)
(represented by Dr. John Herbold)
Dr. J. M. S. Dixon (NACI)
Dr. Theodore C. Eickhoff (ACP)
Dr. Albert W. Pruitt (AMA)

Executive Secretary

Dr. Jeffrey P. Koplan

COMMITTEE MEMBERS ABSENT

Mrs. Betty Bumpers
Dr. William Schaffner II

HHS STAFF PRESENT

FOOD AND DRUG ADMINISTRATION

Center for Drugs and Biologics

Dr. Gerald Quinnan

HHS STAFF PRESENT (continued)

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Care Delivery and Assistance

Dr. Allan Noonan

CENTERS FOR DISEASE CONTROL

Office of the Director

Dr. John E. Jaugstetter
Dr. Gary Noble
Ms. Gwen Strickland-Cid

Center for Infectious Diseases

Ms. Nancy Arden
Dr. Claire Broome
Dr. Carol Ciesielski
Dr. Daniel Fishbein
Dr. Maurice Harmon
Dr. Alan P. Kendal
Dr. Margaret Oxtoby
Dr. Leigh A. Sawyer
Ms. Pamela Yager

Center for Prevention Services

Dr. Roger Bernier
Dr. Edward Brink
Dr. Stephen Cochi
Ms. Ann Funkhouser
Dr. Alan Hinman
Dr. J. Michael Lane
Dr. Ida Onorato
Dr. Walter Orenstein
Dr. Peter Patriarca
Dr. Stephen Preblud

Epidemiology Program Office

Dr. Robert Gunn

OTHERS PRESENT

Dr. Byron Berlin
Dr. Gary J. Bridi
Mr. Robb Chapman
Col. Alfred K. Cheng
Dr. Pinya Cohen
Ms. Cornelia Dekker
Ms. Phyllis Freeman
Dr. Alan Goldschein
Dr. Lance K. Gordon
Dr. Alan Gray
Dr. Jill Hackell
Dr. Victor Jegede
Dr. Cynsie Johnson
Dr. Saul Krugman
Dr. Andre Lamotte
CDR Richard Moore
Dr. Marc Plattner
Ms. Karlyn L. Shedlowski
Dr. Tito R. Ubertini
Dr. Liz Wellman
Col. Robert Wells
Dr. Richard F. White
Dr. Barbara Z. Zajac

The meeting was opened at 8:30 a.m. on February 3 by Dr. Samuel L. Katz. Dr. Elaine Esber represented Dr. Harry Meyer, Jr., FDA, and Dr. John Herbold represented Dr. Jarrett Clinton, Department of Defense.

Influenza Prevention and Control

Dr. Alan Kendal, Division of Viral Diseases (DVD), Center for Infectious Diseases (CID), CDC, introduced the session. Presentations were given by Influenza Branch staff members, Dr. Maurice Harmon, Dr. Karl Kappus, and Ms. Nancy Arden.

Dr. Kappus reviewed current national data on influenza activity. Influenza B and influenza A(H3N2) viruses continued to occur in the United States. Influenza B viruses are more prevalent. For the week ending February 1, 14 states and the District of Columbia reported widespread outbreaks of influenza-like illness, and 18 states reported regional outbreaks. In one outbreak this season, both virus types B and A(H3N2) were isolated. Additional data was presented on influenza virus isolates, by state, for types A(H3N2) and A(H1N1) and indicators of influenza morbidity, by week, in the United States. Reports from WHO National Influenza Centers indicated that influenza A(H3N2), A(H1N1), and B virus isolates were reported from 20 foreign countries since September 1985, with type A(H1N1) isolated rarely.

Dr. Harmon presented information on hemagglutination-inhibition reactions of influenza A(H3N2) viruses (using Ferret serum, A/Bangkok, A/Taiwan, A/Philippines, A/Caen, A/Mississippi and A/USSR) and influenza B viruses (using B/USSR, B/Hong Kong, B/Canada, B/Minnesota, and B/Kanagawa Ferret serum); frequency of identification of influenza B variants between March and December of 1985, tested at the WHO Collaborating Center for Influenza at CDC; hemagglutination-inhibition serum antibody response to influenza vaccine from children in high-risk groups, from adults, and from nursing home residents immunized in the fall of 1985. Results indicated only minor antigenic drift in type A(H3N2) virus, but poor response in vaccinees to current influenza B isolates.

Ms. Arden discussed possible ways of increasing the efficacy of the vaccine for high-risk groups. She reviewed data published by Dr. Barker and colleagues on pneumonia and influenza-associated hospitalizations and deaths among vaccinated and nonvaccinated elderly persons by high-risk status during type A influenza epidemics in 1975-1976 and 1980-1981, and the results of a CDC study in 1982 demonstrating that herd-immunity could probably be achieved in residents of nursing homes. She also presented data supporting the safe and efficacious use of amantadine at 100 mg/day in elderly high-risk residents of a VA chronic-care facility. Finally, she reviewed data published by Dr. Barker on the estimated costs of excess pneumonia and influenza-associated hospitalizations for an epidemic of type A influenza, by age groups. A revised draft of the ACIP statement was then distributed for review and discussion on the following day.

Haemophilus influenzae

Dr. Claire Broome and staff, Division of Bacterial Diseases, CID, gave an update on Haemophilus influenzae type b (Hib) disease and presented surveillance data. A polysaccharide vaccine against systemic Hib, licensed in the United States in April 1985, has been recommended for children at 24 months of age. For children in high-risk groups for Hib disease, including those attending day-care, the vaccine may be administered at the age of 18 months. Volume 34/No 15 of the 1985 MMWR contained ACIP guidelines for its use.

A draft statement updating these recommendations and providing guidelines for the prevention of secondary cases of Hib disease, prepared by the subcommittee (Drs. Mortimer, Katz, Leavitt, Pruitt, and Davis), was mailed to The Committee for their review prior to the meeting. Dr. Theodore Mortimer led a discussion on the draft, especially regarding the efficacy of rifampin prophylaxis and implementation of chemoprophylaxis. The subcommittee will incorporate the suggestions and a recommendation will be issued.

Immunization and Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus (HTLV-III/LAV) Infection

Following lunch, Dr. Alan Hinman, Division of Immunization (DI), Center for Prevention Services (CPS), CDC, discussed possible options regarding the use of live vaccines in persons with HTLV-III/LAV infection. He introduced speakers who would report on HTLV III/LAV.

Dr. Harold Jaffe, AIDS Activity, CID, CDC, presented slides identifying the AIDS virus and discussed the spectrum of AIDS. He also discussed the current epidemiology of adult and pediatric AIDS in the United States.

Dr. Janine Jason, Division of Host Factors, CID, CDC, discussed the immunology of the AIDS virus.

Dr. Pauline Thomas, Surveillance Office of the New York City Department of Health, Bureau of Preventable Diseases, presented an update of pediatric AIDS surveillance in New York City. The study involved 109 children with AIDS, and 71 (65%) known deaths. All cases meet CDC surveillance criteria, including opportunistic infections but excluding children with AIDS-related

complex (ARC). The risk-group data revealed that of the 109 pediatric cases, 86 children (79%) had one/both parent as drug users, 7 (6%) were transfusion associated, 15 (15%) had parents with AIDS. Sixty-seven children (62%) were Black, 33 (30%) were Hispanic, and 9 (8%) were White.

Dr. Thomas reported on three projects regarding the use of live vaccines in HTLV-III infected children. (1) Chart Review Survey - data on 78 infected children born between 1977 and 1985 revealed that 4 had transfusion-associated cases and 74 had acquired illness from an infected mother. Of the 78 children, 75 had received at least one standard vaccine and 74 had received at least one live vaccine. For children with maternally transmitted illness, the average age at onset was 9 months for AIDS patients and 17 months for ARC patients, with average age at diagnosis for AIDS 21 months. (2) Doctor Survey of Opinions and Attitudes - data from 12 doctors regarding use of live vaccines (9 doctors were from private hospitals, 2 from public hospitals, and 1 from the Department of Health) revealed these answers: For a child with AIDS, 12 doctors would give no live vaccine; for a child with ARC, 10 doctors would give no live vaccine (2 doctors were undecided). (3) Options on use of live vaccines:

Option 1. Withhold live vaccines from all known and potentially HTLV-III infected children (children in risk groups) regardless of symptoms.

Option 2. Screen for antibody all children in risk groups and withhold vaccines from the positives.

Option 3. Withhold live vaccines only from children already known to be antibody positive.

Option 4. Give all routine vaccines to all children who lack signs and symptoms of immunodeficiency or ARC.

Dr. Ida Onorato, DI, CPS, CDC, presented a summary of a decision analysis study of the issues of safety and efficacy of live vaccines in persons with HTLV-III/LAV infection and the impact of various options for vaccination.

The Committee agreed not to make a recommendation at this time on the use of live vaccines in persons with HTLV-III/LAV infection.

Poliomyelitis

Dr. Hinman led a discussion of a draft article, "Poliomyelitis: United States, 1975-1984," proposed for publication in the MMWR. The draft was mailed to the Committee for their review prior to the meeting. The article summarizes a review of clinical, laboratory, and epidemiologic data on 150 suspected cases of poliomyelitis reported to CDC from 1975-1984. After a discussion of the draft, Dr. Hinman stated that he would make the suggested changes before releasing it for publication.

Simultaneous Administration of DTP-OPV-MMR

Dr. Hinman reviewed comments on simultaneous administration of DTP-OPV-MMR, which was discussed at the October 24-25, 1985, Committee meeting. A final draft statement will be sent to the Committee for their review and comments.

On day two, the meeting began at 8:30 a.m.

Influenza Prevention and Control (continued from previous day)

Dr. Kendal reviewed background information presented the previous day on prevention and control of influenza and led a discussion of the revised draft recommendation which contained four basic changes in target groups on vaccination strategies: (1) immunization of children receiving long-term aspirin therapy; (2) immunization and amantadine prophylaxis for household members who provide home care for high-risk persons; (3) concurrent administration of influenza vaccine and childhood vaccines; and (4) optimal time for conduct of routine vaccination programs.

Children who receive long-term aspirin therapy and who may be at risk of developing Reye's syndrome following influenza infection should also be considered as priority groups for vaccination against influenza. Immunization of household members who provide care to high-risk persons living at home should also be considered as a means of reducing the chances of exposure of high-risk persons to influenza and to reduce the chances of disruption of care during influenza outbreaks. Maximal impact may be achieved when influenza vaccine is administered from mid-October through December. If vaccine is given much earlier, protection may be waning in many high-risk persons while there is still widespread activity, since in recent years high levels of influenza activity have rarely occurred until January. After the Committee discussed the draft statement, Dr. Kendal asked that any additional changes be sent to him within 2 weeks. He will then make the changes suggested and circulate another draft to the Committee for their review and comments.

New Developments in Rabies Vaccine

Dr. Daniel Fishbein, DVD, CID, reviewed the status of rabies vaccines in the world and human rabies cases from January 1952-December 1984 in the United States. He also discussed the immune complex-like allergic reactions following human diploid cell rabies vaccine (HDCV) boosters.

The main focus of the presentation was Rhesus Diploid Cell Rabies vaccine (RDRV), a new cell culture rabies vaccine for use in humans. The vaccine is expected to be licensed for both pre-exposure and postexposure prophylaxis in the United States in the next few months. Antibody responses and side effects after vaccination with RDRV were discussed. The Committee discussed a draft, "Rhesus Diploid Cell Rabies Vaccine," to supplement the July 20, 1984, ACIP recommendation on Rabies Prevention in the United States. The Committee requested a revision of the draft supplement, incorporating more information on the status of HDCV administered by the intradermal route.

Varicella Zoster

Dr. Katz, Dr. Gerald Quinnan from FDA, and Dr. Barbara Zajac from Merck Sharp & Dohme gave a summary of the January 24, 1986, FDA-sponsored meeting on live, attenuated varicella-zoster virus (OKA strain) vaccine.

Dr. Stephen Preblud, DI, CPS, CDC, summarized for the Committee the currently available surveillance data for varicella cases and other events--MMWR

reports, the National Center for Health Statistics (NCHS) health interview survey, NCHS death certificate data, Professional Activities Study and NCHS hospital discharge data, and National Drug and Therapeutic Index data on physician visits and medication use. He also discussed the possibility of developing selected surveillance sites (similar to those for pertussis), should the vaccine be licensed for general use.

DTP: Japanese Pertussis Vaccine: Delay of Primary Series

Dr. Gary Noble, Assistant Director for Science, CDC, reported that during December 1985 seven Public Health Service scientists--Drs. Noble, Alan Hinman, and Roger Bernier, CDC; Drs. Elaine Esber and Carolyn Hardegree, FDA; Drs. David Klein and Alfred Saah, NIH--went to Japan. They represented the Interagency Group to Monitor Vaccine Development, Production, and Usage. The purpose of the trip was to obtain information about the epidemiology of pertussis and the impact and characteristics of acellular pertussis vaccines used in Japan since 1981. The Group met with staff of the Ministry of Health and Welfare, the National Institute of Health, and university faculty, and visited three pertussis vaccine manufacturing companies in Japan.

Dr. Hinman gave a summary of data obtained during the visit to Japan of the Interagency Group to Monitor Vaccine Development, Production, and Usage. This included data on pertussis cases and deaths from 1947-1984; pertussis rate per 100,000 population and percent of eligible children receiving pertussis vaccine from 1967-1984; summary of adverse events from clinical studies performed and information on claims paid from the compensation system; claims paid by the vaccine compensation system in Japan from 1970-1984 for reactions with and without sequelae; adverse events associated with acellular pertussis vaccines and whole cell pertussis vaccines in Japan; efficacy of acellular vaccines; and changes in age-specific incidence of reported pertussis for ages 0-5 in Japan from 1970-1984.

In 1975 the age of vaccination in Japan was raised to 2 years of age, prior to the introduction of acellular vaccines in 1981. The acellular vaccine has been used in Japan for the last 4 years, and during this time more than 20 million doses have been administered. There has been a continuing decrease in the overall incidence of pertussis from the epidemic peak in 1979, although the reported incidence in 1984 is above the levels of the early 1970s. The incidence of local and febrile reactions is lower after using acellular vaccines than whole cell vaccines previously used in Japan. There is evidence that serious adverse events also have decreased in children 2 years of age and older, the age at which routine pertussis vaccination begins. Several different manufacturers are distributing vaccines that meet the Japanese minimum requirements. Limited data are available regarding clinical efficacy of vaccines produced by individual manufacturers.

Ms. Ann Funkhouser, DI, CPS, CDC, presented an update of a model she reviewed at the April 1985 ACIP meeting on projected pertussis cases with a proposed vaccination schedule in which DTP is initiated at 8 months of age compared to the current schedule. This includes results of baseline analysis in number of cases per year and health outcome with the current and the new vaccine schedule and the differences projected.

The Committee members focused their discussion on the projected increase in chance associations with seizures and the projected increase in pertussis

disease and disease complications under the new proposed vaccine schedule, compared to the decreased chance association of SIDS. In addition, under the proposed new schedule, attributable febrile seizures would likely increase. The increase in serious health outcomes due to the disease were believed to outweigh any projected decrease in chance-associated events. The Committee recommended continuing the present schedule, with initiation of DTP at 2 months of age.

Other ACIP Business

Dr. Koplan distributed to the Committee a copy of Dr. Kevin C. Geraghty's January 30 letter--representing the Ad Hoc Committee of Parents and Physicians for Safe Immunizations--commenting on the national DTP program and DTP-associated reactions.

The next Committee meetings were scheduled for May 12-13 and October 6-7, 1986. Tentative agenda items include rabies, varicella zoster, and hepatitis B.

With the thanks of the Chairman, the meeting was adjourned at 12:30 p.m.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

Samuel L. Katz 25 March 1986

Samuel L. Katz, M.D., Chairman Date